

which is a nucleic acid molecule as activator of cytokine receptors, and a second compound which is a nucleotide sequence encoding 4-1BB ligand or derivative, classified in class 514, subclass 44;

- (III) Claim 26, drawn to a method for treating cancer comprising administering to a subject an effective amount of a first compound which is a cytokine as activator of cytokine receptors, and a second compound which is 4-1BB ligand or derivative, classified in class 514, subclass 12; and
- (IV) Claim 26, drawn to a method for treating cancer comprising administering to a subject an effective amount of a first compound which is a cytokine as activator of cytokine receptors, and a second compound which is a nucleotide sequence encoding 4-1BB ligand or derivative, classified in class 514, subclass 2.

The Examiner contends that the inventions of groups I-IV are distinct from each other. In addition, upon election of one of groups I-IV, the Examiner has required a species. In particular, the Examiner has required that Applicants elect IL-12, IL-15, or IL-18 as a species.

Applicants respectfully traverse the Restriction Requirement and respectfully assert that the restriction of groups I-IV is improper under 35 U.S.C. §121.

Applicants respectfully assert that claim 13 is a proper generic claim and that groups I-IV are more properly characterized as species of a single generic invention. Applicants direct the Examiner's attention to M.P.E.P. §§806.04(b) and 806.04(d) (Eighth Edition, August 2001) for pertinent information pertaining to species elections and the definition of a generic claim. Claim 13 recites a method of treating or preventing cancer in a subject comprising administering to the subject in which such treatment or prevention is desired a therapeutically effective amount of a compound that activates one or more cytokine receptors and a compound that activates one or more co-stimulatory molecules expressed on activated immune cells. Claims 15, 17, 19 and 26-37 in groups I-IV recite particular species of compounds that activate specific cytokine receptors and particular compounds that activate a specific co-stimulatory molecule expressed on activated immune cells. Accordingly, Applicants respectfully request that the requirement for restriction to groups I-IV be modified so that only a species election is required.

Moreover, Applicants respectfully assert that, even assuming, *arguendo*, that groups I-IV represent distinct or independent inventions, to search and examine the subject matter of

groups I-IV together would not be a serious burden on the Examiner. The M.P.E.P. §803 (Eighth Edition, August 2001) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicants respectfully assert that the subject matter of groups I-IV are so intertwined that a single search would identify any relevant art pertaining to a method for treating cancer comprising administering a combination of a compound that activates a cytokine receptor and a compound that activates a co-stimulatory molecule expressed on activated immune cells, regardless of the specific type of compound that activates the cytokine receptor and the specific type of compound that activates the co-stimulatory molecule. Indeed, the Examiner identified groups I-IV as being in the same class and groups I and IV as being in the same subclass. Thus, in view of M.P.E.P. §803, all of the claims of Groups I-IV should be searched and examined in one application. Accordingly, Applicants respectfully request that the Restriction Requirement be withdrawn so that claims 13, 15, 17, 19 and 26-37 are examined in one application.

In order to be fully responsive, however, Applicants hereby provisionally elect, with traverse, to prosecute the claims of group I, without prejudice to Applicants' right to pursue the non-elected subject matter in other applications.

Group I, claims 13, 15, 17, 19 and 26-37, is further subject to the above-mentioned species election requirement. Applicants hereby elect to prosecute IL-12 as the species.

Accordingly, in view of the foregoing, Applicants are provisionally electing, with traverse, to prosecute the claims in group I directed to a method of treating cancer comprising administering to a subject an effective amount of a nucleic acid molecule comprising a nucleotide sequence encoding IL-12 and an effective amount of 4-1BB ligand or a fragment, derivative or analog thereof that activates 4-1BB.¹

¹ Applicants note that the provisional election herein is in accordance with the provisional election in the Preliminary Amendment and Response to Restriction Requirement filed on April 1, 2002 in the United States Patent and Trademark Office (see, page 6 of the Preliminary Amendment and Response to Restriction Requirement).

Entry of the remarks made herein is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

Respectfully submitted,

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